

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V. et al.,

Plaintiffs,

12-cv-2650 (PKC)

-against-

OPINION  
AND ORDER

ALLERGAN, INC. et al.,

Defendants.  
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CASTEL, U.S.D.J.

In 2012, plaintiffs Ferring Pharmaceuticals Inc., Ferring B.V., and Ferring International Center S.A. (“Ferring”) brought claims for correction of inventorship under 35 U.S.C. § 256 to replace Dr. Seymour Fein with two of Ferring’s employees as sole inventors of U.S. Patent Nos. 7,405,203, 7,579,321, and 7,799,761 (“the Fein Patents”), along with related state law claims (Doc 1.) On September 22, 2015, Judge Sweet dismissed plaintiffs’ claims on summary judgment based on equitable estoppel. (Doc 190 (“2015 Decision” or “Ferring I”)<sup>1</sup>.) On January 22, 2019, Judge Sweet issued a claim construction order (“2019 Decision” or “Ferring II”)<sup>2</sup> construing certain claims of the Fein Patents in a separate case (17 cv 9922) that is currently pending before Chief Judge McMahon.<sup>3</sup> Ferring now moves for reconsideration of the 2015 Decision pursuant to Rule 60(b)(5) or (6), Fed. R. Civ. P., arguing that the 2019 Decision created a change in circumstances requiring the vacation of the 2015 Decision.

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<sup>1</sup> Ferring B.V. v. Allergan, Inc., 253 F. Supp. 3d 708 (S.D.N.Y. 2015).

<sup>2</sup> Ferring B.V. v. Serenity Pharm., LLC, 356 F. Supp. 3d 353 (S.D.N.Y. 2019).

<sup>3</sup> Judge Sweet passed away on March 24, 2019. (Doc 360.) The 12 cv 2650 case was reassigned to this Court and the 17 cv 9922 case was reassigned to Chief Judge McMahon. (12 cv 2650 Docket Entry of April 8, 2019; 17 cv 9922 Docket Entry of April 8, 2019.)

For the following reasons, Ferring's motion will be denied.

## LEGAL STANDARD

A district court may grant relief from an order pursuant to Rule 60(b), Fed. R. Civ. P., if, among other reasons, applying an earlier judgment “prospectively is no longer equitable,” or for “any other reason that justifies relief.” Rule 60(b)(5), (6), Fed. R. Civ. P. Rule 60(b) “provides a mechanism for extraordinary judicial relief” under “exceptional circumstances,” Motorola Credit Corp. v. Uzan, 561 F.3d 123, 126 (2d Cir. 2009) (internal quotations omitted), and “[t]he standard for granting such a motion is strict,” Shrader v. CSX Transp., Inc., 70 F.3d 255, 257 (2d Cir. 1995). “A motion for reconsideration should be granted only when [a party] identifies an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice.” Kolel Beth Yechiel Mechil of Tartikov, Inc. v. YLL Irrevocable Trust, 729 F.3d 99, 104 (2d Cir. 2013) (internal quotation marks and citation omitted).

## RELEVANT HISTORY

The Court assumes familiarity with the facts of this case and will not recount anything more than that which is necessary to resolve the present dispute. In April 2012, Ferring sued Serenity Pharmaceuticals Corporation (“Serenity”) and Reprise Biopharmaceutics, LLC (“Reprise”), two companies formed by Dr. Fein, for correction of inventorship of the Fein Patents (Doc 1.) The Fein Patents broadly claim methods of treating nocturnia (frequent nighttime urination) with the anti-diuretic drug desmopressin in a manner to reduce certain unwanted side effects such as hyponatremia (low sodium levels in the blood). (Id. ¶¶125, 138, 153 & Exs. 1-3.) Defendants moved for summary judgment based on equitable estoppel, arguing that Ferring knew about Fein's claims to the inventions for over seven years because Fein's

lawyer, Mr. William Speranza, informed Ferring of Fein's intent to claim patent protection during a series of communications in 2002-2004 known as the "Speranza Correspondence,"<sup>4</sup> and Ferring took no action until 2012. (Doc 133 at 1-5.) Judge Sweet agreed with defendants in the 2015 Decision and dismissed Ferring's claims. Ferring I, 253 F. Supp. 3d at 716-20.

In discussing why equitable estoppel applies to Ferring's claims, Judge Sweet stated the following:

[I]n his correspondence with Ferring, Mr. Speranza explicitly referred to "low dosage" applications of desmopressin as Fein's inventions. Ferring's response to Fein's claim of inventorship was not that the low-dosage invention was Ferring's intellectual property, but that it was not patentable at all, and that Ferring would no longer be pursuing claims directed toward it. Ferring's present application to correct inventorship contradicts its earlier position in the Speranza correspondence. The low-dosage invention as described in the PCT at issue in the Speranza correspondence is the same subject matter detailed in the patents-in-suit, down to the specific numerical quantity of desmopressin to be used. Consequently, this case is distinguishable from Radio Systems [Corp. v. Lalor], 709 F.3d 1124 (Fed. Cir. 2013)], where the patent not covered by equitable estoppel was held to contain claims "different in scope" from those of the patents that were the focus of the misleading communication.

Despite having threatened immediate legal action with respect to the patent application, Ferring did not disagree or otherwise challenge Mr. Speranza's assertion that low dosage development was Fein's intellectual property. Ferring was aware of two Fein patent applications that include claims for low desmopressin doses and low desmopressin plasma concentration levels. Ferring's December 9, 2004 letter reflects that the parties were discussing Dr. Fein's 2003 PCT application. Then, on December 14, 2004, Mr. Speranza sent [Ferring's counsel] Dr. Fein's first U.S. patent application. Both of those applications contained claims for specific low doses and specific low plasma concentration levels. In sum, Ferring's inaction satisfies the misleading communication prong under [the test for equitable estoppel].

Id. at 718 (citations omitted).

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<sup>4</sup> For a fuller recitation of the Speranza Correspondence, see Ferring I, 253 F. Supp. 3d at 712-15.

In April 2017, Ferring filed a separate action against Serenity, Reprise, and others seeking a declaration of invalidity and unenforceability of the Fein Patents. (17 cv 9922 Doc 1.) The case was also assigned to Judge Sweet after being transferred from the District of Delaware to this district. (17 cv 9922 Doc 67.) As part of that case, Judge Sweet issued an order construing certain claims of the Fein Patents in January 2019. Ferring II, 356 F. Supp. 3d 353.

Relevant here, the Court in the 2019 Decision reviewed the parties' proposed construction of the term "a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/serum concentration no greater than 10 pg/ml" found in claim 1 of the '203 Patent. Id. at 362. The Court declined to construe the phrase to read in a dose limitation as argued for by Ferring, instead stating that it "requires no construction." Id. In making this determination, it noted that the '203 Patent did not claim specific dosages that corresponded to blood/plasma levels and that Fein "expressly amended" claims in his original applications to remove dose-specific language and remove the word "low" from the phrase "low dose" in claim 19 of the '203 Patent. Id. at 365.

## DISCUSSION

Ferring argues that the Court should vacate the 2015 Decision because there has been a "change to the foundational basis of that judgment." (Ferring Rule 60(b) Mot. at 4; Doc 374). Specifically, Ferring argues that the 2015 Decision granted equitable estoppel based on a determination that Fein relied on Ferring's "misleading conduct or silence" that Ferring would not pursue rights to a "low dosage invention" as discussed in the Speranza Correspondence. (Id. at 6-13). But, Ferring claims, the 2019 Decision construed the claims of the Fein Patents more broadly than the "low dosage invention" described in the Speranza Correspondence. Therefore, any silence or misconduct on the part of Ferring as related to the narrower invention should not

estop Ferring from pursuing claims of inventorship with respect to the more expansive invention which Judge Sweet construed the Fein Patents to contain in 2019.

This is not an “exceptional circumstance” warranting the vacatur of the 2015 Decision. Uzan, 561 F.3d at 126. The Court disagrees with Ferring’s understanding of both the 2015 Decision and the 2019 Decision. The 2015 Decision, contrary to Ferring’s assertions, did not “rel[y] on the Speranza Correspondence’s characterization of the alleged invention as being directed to ‘low dose’ desmopressin.” (Doc 374 at 10.) The 2015 Decision did not limit Fein’s proposed invention to low dose desmopressin. For example, it states that Fein provided Ferring with copies of his Patent Cooperation Treaty (“PCT”) Application US2003/014463 and his first U.S. Patent Application 10/706,100. Ferring I, 253 F. Supp. 3d at 718. These applications described and made Ferring “aware of” Fein’s claims for “low desmopressin doses and low desmopressin plasma concentration levels,” along with various routes of administration amongst other proposed inventive concepts. Id. at 716, 718; see Doc 383 Ex. B (‘100 Patent Application); Ex. F (US2003/014463 PCT Application). While characterizing Fein’s invention as “low dosage” at times throughout the discussion, see, e.g., Ferring I, 253 F. Supp. 3d. at 717, 718, the opinion recognizes that overall Fein presented the “same subject matter” that formed the basis for the Fein Patents to Ferring in 2004 and was met with silence. Id. at 718.<sup>5</sup>

The 2019 Decision does not provide a basis for determining that the 2015 Decision “prospectively is no longer equitable” and should be vacated. Rule 60(b)(5), (6). Ferring argues the 2019 Decision construed the term “dose” as not limited to “low dose,” expanding claim scope from that which formed the basis for the 2015 Decision’s grant of

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<sup>5</sup> As Serenity and Reprise note, the PCT and U.S. Patent Application at issue in the Speranza Correspondence contain dependent claims that do not identify any numerical quantities or dosages of desmopressin of which Ferring was aware. See Doc 383 Ex. B at 16 claims 8, 9 (‘100 Patent Application); Ex. F at 32-33 claims 8, 9 (US2003/014463 PCT Application).

estoppel. (Doc 374 at 12.) The 2019 Decision did not expand the scope of the claims of the Fein Patents because Judge Sweet held that the disputed claim term (claim 1 of the '203 Patent) “dose of desmopressin sufficient to achieve a maximum desmopressin plasma/serum concentration no greater than 10 pg/ml” “requires no construction.” Ferring II, 356 F. Supp. 3d at 362.<sup>6</sup> In discussing why the claim did not require construction, Judge Sweet noted that Fein had amended the language of the '203 Patent to remove the word “low” from the phrase “low dose” and removed dose-specific language. Id. at 365. This statement did not create a change in the law or the scope of the patent claims, most notably because it is not a construction of any claim but an observation on prosecution history. Even after noting this development, Judge Sweet continues to describe Fein’s invention as a “low dose discovery” in the 2019 Decision, confirming that he understood reduced levels of desmopressin to be part of Fein’s invention. Id.; see id. (stating in reference to the claim limitation of a blood/plasma concentration level “no greater than 10 pg/ml” that there exists a “linear relationship between dosage of desmopressin and blood/plasma concentration”).

Ferring also argues that the 2015 Decision did not determine that Fein’s invention included blood/plasma concentration levels and that the 2019 Decision expanded claim scope by “adopt[ing] the arguments” that the Fein Patents “claim only the low plasma concentrations.” (Doc 374 at 13; see id. at 6.) But again, the section of the 2019 Decision Ferring relies on did not construe any claim term, see Ferring II, 356 F. Supp. 3d at 362-65, and, as discussed, the 2015 Decision acknowledged that Fein’s inventions included claims for “low desmopressin plasma concentration levels,” Ferring I, 253 F. Supp. 3d at 718.

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<sup>6</sup> Ferring notes that Judge Sweet made “parallel findings” for other claim terms reciting desmopressin concentration. (Doc 374 at 13 n.4 (giving as an example claim 10 of the '203 Patent)); see Ferring II, 356 F. Supp. 3d at 365–66.

Ferring principally relies on Radio Systems, 709 F.3d 1124 (Fed. Cir. 2013), and John Bean Technology Corporation v. Morris and Associates, 887 F.3d 1322 (Fed. Cir. 2018), in support of its argument. Both are distinguishable. In John Bean, the Federal Circuit overturned a district court decision finding a party equitably estopped from asserting claims of infringement. The Federal Circuit stated that “because the asserted claims did not exist at, or were substantively altered since” the time the parties discussed their intellectual property rights, “John Bean could not have engaged in misleading conduct or silence with respect to those claims.” 887 F.3d at 1328.

Similarly, in Radio Systems, the Federal Circuit reversed a district court’s grant of equitable estoppel where the claims in a continuation-in-part patent were issued several years after the misleading conduct. 709 F.3d at 1131. The Federal Circuit held that because “the patents contain claims of different scope” than the claims that were the focus of the allegedly misleading conduct, they could not give rise to equitable estoppel. Id.

Here, as stated above, the 2019 Decision did not construe claim 1 of the ’203 Patent or otherwise alter claim scope to expand the scope of desmopressin dosing or blood/plasma concentration levels. Unlike in John Bean or Radio Systems, there is no substantive alteration of the claims here between the 2015 and 2019 Decisions.

Chief Judge McMahon, in the case from which Judge Sweet’s 2019 Decision issued, rejected similar arguments made by Ferring in an opinion issued in June 2019. See Ferring B.V. v. Serenity Pharm, LLC, 17 cv 9922 (CM), 2019 WL 2590732, at \*8-9, \*15 (S.D.N.Y. June 12, 2019). There, Ferring attempted to relitigate the issue of inventorship of the Fein Patents and was collaterally estopped from doing so. Judge McMahon determined, contrary to Ferring’s proposed interpretation of the 2015 Decision, that Judge Sweet “specifically

recognized that the inventions for which Dr. Fein sought patent protection . . . included claims directed to low plasma concentrations without specific numerical dosage limitations” and that “Judge Sweet did not conclude that Dr. Fein reasonably relied on Ferring’s acquiescence to Dr. Fein pursuing patent protection *only* for the low dosage possibilities.” *Id.* at \*9; *see id.* at \*15 (further stating that the 2015 Decision “was not limited to a ‘low dose’ invention” and “included the inventive features establishing low plasma/serum levels”).

Ferring adds two additional reasons this Court should vacate the 2015 Decision – (1) the 2019 Decision creates a material issue of fact as to the scope of the claims in the Fein Patents, and (2) because, as of April 2019, no party had the rights to commercialize the Fein Patents, there is a material dispute of fact as to which party, if any, would be prejudiced if Ferring were allowed to continue to assert infringement claims. *See John Bean*, 887 F.3d at 1327 (listing prejudice of the accused infringer as one of the three elements of equitable estoppel).

As to the first argument, the Court has already explained why there is no genuine dispute on the scope of claim 1 of the ’203 Patent or claims containing parallel terms for purposes of the equitable estoppel determination. Ferring presents no argument that the scope of any other claim of the Fein Patents provides reason to vacate the 2015 Decision.

As to the second argument, any lapse in current commercialization, which is not in dispute, is not inconsistent with Judge Sweet’s 2015 determination that Serenity and Reprise would be prejudiced by an infringement action because they would risk losing the ability to prevent competitors from practicing the patents and non-recoverable investments which were made while reasonably relying on Ferring’s misleading representations. *Ferring I*, 253 F. Supp. 3d at 720. Even without a commercial partner, Serenity and Reprise would face prejudice in

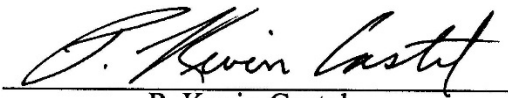


their search for a replacement partner if they had the threat of an infringement action looming.  
Ferring's additional arguments do not persuade the Court to grant Ferring the relief sought.

#### CONCLUSION

Ferring's motion for reconsideration is DENIED. The Clerk is directed to terminate the motion (Doc 373.)

SO ORDERED.

  
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P. Kevin Castel  
United States District Judge

Dated: New York, New York  
July 18, 2019